

## CLIENT SERVICE MANUAL



DIATHERIX®

*Linking Diagnostics to Therapeutics™*

[ Revised – 01.16.15 ]

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# DIRECTORY

## Diatherix Laboratories, Inc.

601 Genome Way, Suite 2100  
Huntsville, Alabama 35806  
CLIA ID Number: 01-D1085737

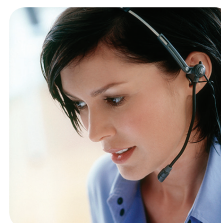
**Chairman and CEO:** Dennis Grimaud  
**President and COO:** Randy Ward, M.T. (ASCP)  
**VP of Operations & Laboratory Director:** Donald R. Stalons, Ph.D., D(ABMM), MPH  
**Medical Director:** Frank Honkanen, M.D.



Diatherix Laboratories is located in the  
**HudsonAlpha Institute for Biotechnology**  
in Cummings Research Park, Huntsville, AL.

## Client Services

**Toll free:** 866.979.4242  
**Fax:** 256.327.0984  
**Hours:** 8:00 - 5:30 CST Monday - Friday  
8:30 - 5:00 CST Saturday  
  
**Compliance Hotline (anonymous):** 256.327.5222



## Billing Department

**Toll free:** 866.829.1854  
**Fax:** 256.327.5259  
**Hours:** 8:00 - 4:30 CST Monday - Friday



## Supplies & Shipping

**Toll free:** 877.820.8047 (voice mail monitoring until 8:00pm CST)  
**Fax:** 256.327.9858  
**Email:** supplies@diatherix.com  
  
**FedEx:** 1.800.463.3339 (Press 0 for the first three prompts to reach an operator)



## ABOUT DIATHERIX

Diatherix is an innovative, CLIA-certified, molecular diagnostic laboratory utilizing proprietary **TEM-PCR™** (Target Enriched Multiplex Polymerase Chain Reaction) technology for precise detection of infectious diseases – **linking diagnostics to therapeutics.**

### Diatherix Distinctions:

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- *Simultaneous identification of bacteria, viruses, parasites, Candida and selected antibiotic resistance genes*
- *Detection of bacteria in the presence of antibiotics*
- *Increased sensitivity and specificity*
- *Simplicity of single sample collection*
- *One day results\**

\*Determined by sample receipt.

### TEM-PCR Benefits:

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TEM-PCR technology is a unique, multiplex amplification platform designed to overcome the challenges that exist with conventional laboratory methods and real-time PCR applications.

Improved speed and accuracy of laboratory results lead to:

- *Improved patient outcomes*
- *Cost reduction and avoidance*
- *Reduced antibiotic utilization*
- *Increased patient satisfaction*
- *Greater clinical value*

### Billing:

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Billing for laboratory services has become complicated and unpredictable due to the increased number of plans with different co-pays and deductibles. Much like your business, it is difficult to know in advance what a specific insurance plan will cover for a patient, and therefore what may be the patient's responsibility.

Diatherix is dedicated to assisting patients with billing questions. If a patient requires assistance, please ask them to call our Billing Department at **866.829.1854**.



# SPECIMEN PREPARATION INSTRUCTIONS

– **Please read all instructions for collecting and shipping of specimens before beginning the collection process.**

1. Choose the appropriate Diatherix test panel. **Pages 8-18**
2. Follow the appropriate specimen collection procedure. **Pages 19-24**
  - *Specimen collection protocols in this manual are those that are recommended for each of the panels that Diatherix offers. Substitution of collection kit components or specimen types must be preapproved by Diatherix before the specimen is submitted for testing.*
3. Prevent specimen rejection:
  - *Make sure the top is seated properly and screwed down tightly on the tube.*
  - *Label the specimen transfer tube with two identifiers. Preferred identifiers are the patient's first and last name and barcode label from the requisition. This name and barcode must match the name and barcode on the requisition.\**



4. Fill out all required fields on the requisition. Writing must be legible.
5. Package and ship the specimen and requisition according to instructions. **Page 5**

\* Other examples of acceptable identifiers include: date of birth, hospital number, social security number, unique random number. Each of the two identifiers must match on the tube and the requisition.

## Requirements for Acceptance of Specimen

Specimens must be:

- appropriate for the test requested.
- accompanied by a properly completed, legible Diatherix Laboratory Request.
- transported to the lab according to packaging and shipping instructions.
- in a properly sealed biohazard specimen bag.
- labeled with two identifiers, preferably with the patient's name and barcode label which matches the requisition.
- intact, in the proper container and not leaking.
- in the appropriate specimen transport media.
- within the specimen transport stability range of 5 days, at ambient temperature, measured from time of collection to the time of receipt for laboratory testing. (For ThinPrep® pap solution, the specimen transport stability range is 30 days.)

*Clients will be contacted as soon as possible if any issues need to be resolved.*

**Results are typically reported the same day our laboratory receives the specimen.**

## PACKAGING / SHIPPING INSTRUCTIONS

- **Specimens for all test panels should be shipped at ambient temperature.**
- **Each biohazard bag must contain only one patient sample.**

- 1 Place the labeled transport tube in the zippered pouch in the front of the biohazard bag with the absorbent pad. Seal the bag.
- 2 Fold and place the completed Diatherix Test Requisition in the flap pocket (no zipper) in the back of the biohazard transport bag.

*Verify that the sample tube and the requisition are in the correct pouch:*

- Requisition is located in the pouch on the back side of the bag
- Specimen sample is located in the front side in the zippered pouch

- 3 Place the biohazard specimen bag(s), each containing only one sample, in the Diatherix specimen shipping box.

*More than one specimen bag may be shipped in the same box.*

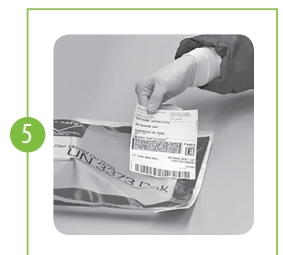
- 4 Place the Diatherix specimen shipping box(s) into the FedEx® UN 3373 Clinical Pak and seal it.

*More than one box may be placed in the Clinical Pak.*

- 5 Apply the barcoded shipping label to the FedEx® UN 3373 Clinical Pak. Detach and retain the top portion of the shipping label for your records.
- 6 Call **1-800-463-3339** (1-800-GOFEDEX) to schedule a pickup. Listen to the automated system until after it states “*in a few words please describe what you are calling about.*” Then, press 0 for the next three prompts to be connected to an operator. State that you have an *Express Prepaid Label* and provide your address. No other information will be needed.

*If your package cannot be picked up, it may be placed in a FedEx® Drop Box. A FedEx® Drop Box can be located by calling FedEx® or going to FedEx.com. **Do not take this package to a FedEx® Office location as they will not accept this type of shipment.***

**TIP:** For your records, write the pickup confirmation number in the space provided on the confirmation label.



# DIATHERIX PANEL LIST

## Viral Respiratory

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus

## Bacterial Pneumonia

*Acinetobacter baumannii*  
*Bordetella pertussis*  
*Chlamydophila pneumoniae*  
*Haemophilus influenzae*  
*Haemophilus influenzae* (Type B)  
*Klebsiella pneumoniae*  
*Legionella pneumophila*  
MRSA<sup>1</sup>  
PVL<sup>2</sup> gene  
*Moraxella catarrhalis*  
*Mycoplasma pneumoniae*  
*Neisseria meningitidis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes* (Group A)  
+ Antibiotic resistance genes\*

## Atypical Pneumonia

*Bordetella pertussis*  
*Chlamydophila pneumoniae*  
*Legionella pneumophila*  
*Mycoplasma pneumoniae*

## Influenza

Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4

## Respiratory Infection

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
*Acinetobacter baumannii*  
*Bordetella pertussis*  
*Chlamydophila pneumoniae*  
*Haemophilus influenzae*  
*Haemophilus influenzae* (Type B)  
*Klebsiella pneumoniae*  
*Legionella pneumophila*  
MRSA<sup>1</sup>  
PVL<sup>2</sup> gene  
*Moraxella catarrhalis*  
*Mycoplasma pneumoniae*  
*Neisseria meningitidis*  
*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes* (Group A)  
+ Antibiotic resistance genes\*

## Ear Nose & Throat

*Acinetobacter baumannii*  
*Chlamydophila pneumoniae*  
*Enterobacter aerogenes*  
*Enterobacter cloacae*  
*Haemophilus influenzae*  
*Haemophilus influenzae* (Type B)  
*Klebsiella pneumoniae*  
MRSA<sup>1</sup>  
PVL<sup>2</sup> gene  
*Moraxella catarrhalis*  
*Mycoplasma pneumoniae*  
*Neisseria meningitidis*  
*Proteus mirabilis*  
*Pseudomonas aeruginosa*  
*Serratia marcescens*  
*Staphylococcus aureus*  
*Stenotrophomonas maltophilia*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes* (Group A)  
+ Antibiotic resistance genes\*

## Upper Respiratory Infection

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Rhinovirus  
*Haemophilus influenzae*  
*Haemophilus influenzae* (Type B)  
*Moraxella catarrhalis*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes* (Group A)

## Pediatric Respiratory

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human bocavirus  
Human coronavirus (4 types)  
Human metapneumovirus  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
*Bordetella pertussis*  
*Chlamydophila pneumoniae*  
*Haemophilus influenzae*  
*Haemophilus influenzae* (Type B)  
*Moraxella catarrhalis*  
*Mycoplasma pneumoniae*  
*Neisseria meningitidis*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes* (Group A)

## Pharyngitis

Adenovirus types 3, 4, 7, 21  
Enterovirus group  
Human coronavirus (4 types)  
Influenza A - Human influenza  
Influenza A - H1N1-09  
Influenza B  
Parainfluenza virus 1, 2, 3, 4  
Respiratory Syncytial Virus  
Rhinovirus  
*Chlamydophila pneumoniae*  
*Mycoplasma pneumoniae*  
*Streptococcus pyogenes* (Group A)

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin

# DIATHERIX PANEL LIST

## Sexually Transmitted Disease

*Atopobium vaginae*  
*Chlamydia trachomatis*  
*Gardnerella vaginalis*  
*Mycoplasma genitalium*  
*Mycoplasma hominis*  
*Neisseria gonorrhoeae*  
*Trichomonas vaginalis*  
*Ureaplasma urealyticum*

## CT + NG + *T. vaginalis*

*Chlamydia trachomatis*  
*Neisseria gonorrhoeae*  
*Trichomonas vaginalis*

## Bacterial Vaginosis

*Atopobium vaginae*  
*Gardnerella vaginalis*  
*Mycoplasma genitalium*  
*Mycoplasma hominis*  
*Ureaplasma urealyticum*

## Herpes Simplex Virus

Herpes Simplex Virus type 1  
Herpes Simplex Virus type 2

## Candidiasis

*Candida albicans*  
*Candida glabrata*  
*Candida krusei*  
*Candida parapsilosis*  
*Candida tropicalis*

## HPV High Risk Typing

HPV High Risk types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 67, 68

## Group B *Streptococcus*

Group B *Streptococcus*  
(*Streptococcus agalactiae*)

## Infectious Disease

*Acinetobacter baumannii*  
*Enterobacter aerogenes*  
*Enterobacter cloacae*  
*Enterococcus faecalis*  
*Enterococcus faecium*  
*Escherichia coli*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*  
*Pseudomonas aeruginosa*  
*Serratia marcescens*  
*Streptococcus pyogenes* (Group A)  
MRSA<sup>1</sup>  
*Staphylococcus aureus*  
PVL<sup>2</sup> gene  
MRCoNS<sup>3</sup>  
Coagulase-Negative *Staphylococci*  
*Staphylococcus epidermidis*  
+ Antibiotic resistance genes\*  
+ Vancomycin resistance

## Staph. Differentiation

MRSA<sup>1</sup>  
*Staphylococcus aureus*  
PVL<sup>2</sup> gene  
MRCoNS<sup>3</sup>  
Coagulase-Negative *Staphylococci*  
*Staphylococcus epidermidis*  
+ Antibiotic resistance genes\*

## Urinary Tract Infection

*Enterobacter cloacae*  
*Enterococcus faecalis*  
*Escherichia coli*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*  
*Pseudomonas aeruginosa*

## *C. difficile*

*Clostridium difficile* (Toxin B gene)

## Gastrointestinal

*Campylobacter jejuni*  
*Clostridium difficile* (Toxin B gene)  
Enterohemorrhagic *E. coli* (EHEC)  
- Shiga-like toxin gene (*stx1*)  
- Shiga-like toxin gene (*stx2*)  
Enteroinvasive *E. coli/Shigella* (EIEC)  
Enteropathogenic *E. coli* (EPEC)  
Enterotoxigenic *E. coli* (ETEC)  
*Salmonella enterica*  
*Vibrio parahaemolyticus*  
Adenovirus 40, 41  
Norovirus  
Rotavirus  
*Cryptosporidium parvum*  
*Giardia lamblia*

## \*Antibiotic Resistance Genes

Aminoglycosides  
Cephalosporin (Staphylococcal)  
Erythromycin/Clindamycin  
Methicillin (Staphylococcal)  
Tetracycline

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin

<sup>3</sup> Methicillin-resistant Coagulase-Negative *Staphylococci*



# DIATHERIX TEST PANELS

## ATYPICAL PNEUMONIA PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Bordetella pertussis</i>	<i>Legionella pneumophila</i>
<i>Chlamydophila pneumoniae</i>	<i>Mycoplasma pneumoniae</i>

### Collection Procedures:

Bronchial Aspirate.....	21
Sputum Specimen Swab.....	21
Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20

## BACTERIAL PNEUMONIA PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Acinetobacter baumannii</i>	MRSA <sup>1</sup>
<i>Bordetella pertussis</i>	PVL <sup>2</sup> gene
<i>Chlamydophila pneumoniae</i>	<i>Mycoplasma pneumoniae</i>
<i>Haemophilus influenzae</i>	<i>Neisseria meningitidis</i>
<i>Haemophilus influenzae</i> (Type B)	<i>Pseudomonas aeruginosa</i>
<i>Klebsiella pneumoniae</i>	<i>Staphylococcus aureus</i>
<i>Legionella pneumophila</i>	<i>Streptococcus pneumoniae</i>
<i>Moraxella catarrhalis</i>	<i>Streptococcus pyogenes</i> (Group A)

### Antibiotic Resistance Genes:

Aminoglycosides  
Cephalosporin (Staphylococcal)  
Erythromycin/Clindamycin  
Methicillin (Staphylococcal)  
Tetracycline

### Collection Procedures:

Bronchial Aspirate.....	21
Sputum Specimen Swab.....	21
Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin

# DIATHERIX TEST PANELS

## BACTERIAL VAGINOSIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Atopobium vaginae</i>	<i>Mycoplasma hominis</i>
<i>Gardnerella vaginalis</i>	<i>Ureaplasma urealyticum</i>
<i>Mycoplasma genitalium</i>	

### Collection Procedure:

Vaginal Swab .....24

## BRONCHITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	Parainfluenza virus types 1, 2, 3, 4	<i>Haemophilus influenzae</i> (Type B)
Human coronavirus (4 types)	Respiratory Syncytial Virus	<i>Klebsiella pneumoniae</i>
Human metapneumovirus	Rhinovirus	<i>Moraxella catarrhalis</i>
Influenza A - Human influenza	<i>Bordetella pertussis</i>	<i>Mycoplasma pneumoniae</i>
Influenza A - H1N1-09	<i>Chlamydophila pneumoniae</i>	<i>Pseudomonas aeruginosa</i>
Influenza B	<i>Haemophilus influenzae</i>	<i>Streptococcus pneumoniae</i>

### Collection Procedures:

Bronchial Aspirate.....21  
Sputum Specimen Swab .....21  
Nasopharyngeal Aspirate/Wash...20  
Nasopharyngeal Swab .....20

## CANDIDIASIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Candida albicans</i>	<i>Candida parapsilosis</i>
<i>Candida glabrata</i>	<i>Candida tropicalis</i>
<i>Candida krusei</i>	

### Collection Procedures:

Vaginal Swab.....24  
ThinPrep® Pap Solution.....21  
Endocervical Swab .....23

# DIATHERIX TEST PANELS

## CT + NG + *T. VAGINALIS* PANEL

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This panel utilizes TEM-PCR to detect molecular targets that identify:

*Chlamydia trachomatis*  
*Neisseria gonorrhoeae*  
*Trichomonas vaginalis*

### Collection Procedures:

Endocervical Swab .....23  
Vaginal Swab.....24  
ThinPrep® Pap Solution.....21  
Male Urethral Swab .....24  
Urine Specimen for STD Testing...23

**DISCLAIMER:** The Diatherix Laboratories Sexually Transmitted Disease Panels are not recommended for evaluation of suspected sexual abuse or for other medico-legal indications.

**NOTE:** Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

## *CLOSTRIDIUM DIFFICILE* TOXIN B GENE

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This assay utilizes TEM-PCR to detect a molecular target that identifies:

*Clostridium difficile* Toxin B gene

### Collection Procedures:

Stool Specimen Swab .....21  
Rectal Swab .....21

# DIATHERIX TEST PANELS

## EAR NOSE & THROAT PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Acinetobacter baumannii</i>	<i>Mycoplasma pneumoniae</i>
<i>Chlamydophila pneumoniae</i>	<i>Neisseria meningitidis</i>
<i>Enterobacter aerogenes</i>	<i>Proteus mirabilis</i>
<i>Enterobacter cloacae</i>	<i>Pseudomonas aeruginosa</i>
<i>Haemophilus influenzae</i>	<i>Serratia marcescens</i>
<i>Haemophilus influenzae</i> (Type B)	<i>Staphylococcus aureus</i>
<i>Klebsiella pneumoniae</i>	<i>Streptococcus pneumoniae</i>
<i>Moraxella catarrhalis</i>	<i>Streptococcus pyogenes</i> (Group A)
MRSA <sup>1</sup>	
PVL <sup>2</sup> gene	

### Antibiotic Resistance Genes:

Aminoglycosides  
Cephalosporin (Staphylococcal)  
Erythromycin/Clindamycin  
Methicillin (Staphylococcal)  
Tetracycline

### Collection Procedures:

Throat Swab .....	19
Ear Swab .....	19
Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20

## GASTROINTESTINAL PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Campylobacter jejuni</i>	Enteroinvasive <i>E. coli</i> /Shigella (EIEC )	Adenovirus types 40, 41
<i>Clostridium difficile</i> (Toxin B gene)	Enteropathogenic <i>E. coli</i> (EPEC)	Norovirus
Enterohemorrhagic <i>E. coli</i> (EHEC)	Enterotoxigenic <i>E. coli</i> (ETEC)	Rotavirus
- Shiga-like toxin gene ( <i>stx1</i> )	<i>Salmonella enterica</i>	<i>Cryptosporidium parvum</i>
- Shiga-like toxin gene ( <i>stx2</i> )	<i>Vibrio parahaemolyticus</i>	<i>Giardia lamblia</i>

### Collection Procedures:

Stool Specimen Swab .....	21
Rectal Swab .....	21

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin



# DIATHERIX TEST PANELS

## GROUP B STREPTOCOCCUS

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This assay utilizes TEM-PCR to detect molecular targets that identify:

Group B *Streptococcus* (*Streptococcus agalactiae*)

### Collection Procedure:

Vaginal/Rectal Swab .....22

**NOTE:** It is strongly recommended by CDC that a vaginal/rectal swab be collected for pregnant women. Cervical specimens are not recommended and a speculum should not be used for swab collection.

The ESwab™ transport tube (white top) must be used. **Do not use the STD-Genital Health Collection Kit (orange top tube).**

Antibiotic susceptibility testing is available on GBS by request. Susceptibility testing can only be performed when the white top ESwab™ tube is used for transport. **Specimen stability for susceptibility is two days at ambient Temperature.**

The GBS sample will be inoculated into a broth supplement overnight if negative on the first day it is tested. It will then be tested again the second day after incubation. This is a CDC recommendation.

## HERPES SIMPLEX VIRUS PANEL

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This panel utilizes TEM-PCR to detect molecular targets that identify:

Herpes Simplex Virus 1

Herpes Simplex Virus 2

### Collection Procedures:

General swab (eye, lesion, etc) ....19

ThinPrep® Pap Solution.....21

**NOTE:** Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

ThinPrep® pap solution is stable for 30 days.

HSV Panel can also be tested with the swab specimen or urine specimen collected with the Diatherix Genital Health Collection Kit to test along with the STD Panel.

# DIATHERIX TEST PANELS

## HPV HIGH RISK TYPING PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

**HPV High Risk types:** 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 67, 68

### Collection Procedures:

Endocervical Swab .....	23
ThinPrep® Pap Solution .....	21
Throat Swab .....	19

**NOTE: Urine specimens are not acceptable.** ThinPrep® pap solution is stable for 30 days.

## INFECTIOUS DISEASE PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

*Acinetobacter baumannii*  
*Enterobacter aerogenes*  
*Enterobacter cloacae*  
*Enterococcus faecalis*  
*Enterococcus faecium*  
*Escherichia coli*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*  
*Pseudomonas aeruginosa*

*Serratia marcescens*  
*Streptococcus pyogenes* (Group A)  
MRSA<sup>1</sup>  
*Staphylococcus aureus*  
PVL<sup>2</sup> gene  
MRCoNS<sup>3</sup>  
Coagulase-Negative *Staphylococci*  
*Staphylococcus epidermidis*

### Antibiotic Resistance Genes:

Aminoglycosides  
Cephalosporin (Staphylococcal)  
Erythromycin/Clindamycin  
Methicillin (Staphylococcal)  
Tetracycline  
Vancomycin

### Collection Procedures:

General Swab (wound, etc) .....	19
Clean Catch Urine Specimen .....	22
Synovial Fluid .....	21

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Panton-Valentine leukocidin

<sup>3</sup> Methicillin-resistant Coagulase-Negative *Staphylococci*

# DIATHERIX TEST PANELS

## INFLUENZA PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Influenza A - Human influenza	Influenza B
Influenza A - H1N1-09	Parainfluenza virus types 1, 2, 3, 4

### Collection Procedures:

Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20
Throat Swab .....	19
Bronchial Aspirate.....	21
Sputum Specimen Swab .....	21

## PEDIATRIC RESPIRATORY PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	Influenza B	<i>Haemophilus influenzae</i> (Type B)
Enterovirus group	Parainfluenza virus types 1, 2, 3, 4	<i>Moraxella catarrhalis</i>
Human bocavirus	Respiratory Syncytial Virus	<i>Mycoplasma pneumoniae</i>
Human coronavirus (4 types)	Rhinovirus	<i>Neisseria meningitidis</i>
Human metapneumovirus	<i>Bordetella pertussis</i>	<i>Streptococcus pneumoniae</i>
Influenza A - Human influenza	<i>Chlamydophila pneumoniae</i>	<i>Streptococcus pyogenes</i> (Group A)
Influenza A - H1N1-09	<i>Haemophilus influenzae</i>	

### Collection Procedures:

Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20
Bronchial Aspirate.....	21
Sputum Specimen Swab .....	21

# DIATHERIX TEST PANELS

## PHARYNGITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	Influenza A - H1N1-09	Rhinovirus
Enterovirus group	Influenza B	<i>Chlamydophila pneumoniae</i>
Human coronavirus (4 types)	Parainfluenza virus types 1,2,3,4	<i>Mycoplasma pneumoniae</i>
Influenza A - Human influenza	Respiratory Syncytial Virus	<i>Streptococcus pyogenes</i> (Group A)

### Collection Procedures:

Throat Swab .....	19
Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20

## RESPIRATORY INFECTION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	<i>Bordetella pertussis</i>	<i>Staphylococcus aureus</i>
Enterovirus group	<i>Chlamydophila pneumoniae</i>	<i>Streptococcus pneumoniae</i>
Human bocavirus	<i>Haemophilus influenzae</i>	<i>Streptococcus pyogenes</i> (Group A)
Human coronavirus (4 types)	<i>Haemophilus influenzae</i> (Type B)	
Human metapneumovirus	<i>Klebsiella pneumoniae</i>	
Influenza A - Human influenza	<i>Legionella pneumophila</i>	
Influenza A - H1N1-09	<i>Moraxella catarrhalis</i>	
Influenza B	MRSA <sup>1</sup>	
Parainfluenza virus types 1, 2, 3, 4	PVL <sup>2</sup> gene	
Respiratory Syncytial Virus	<i>Mycoplasma pneumoniae</i>	
Rhinovirus	<i>Neisseria meningitidis</i>	
<i>Acinetobacter baumannii</i>	<i>Pseudomonas aeruginosa</i>	

### Antibiotic Resistance Genes:

Aminoglycosides  
Cephalosporin (Staphylococcal)  
Erythromycin/Clindamycin  
Methicillin (Staphylococcal)  
Tetracycline

### Collection Procedures:

Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20
Bronchial Aspirate.....	21
Sputum Specimen Swab .....	21

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin



# DIATHERIX TEST PANELS

## RHINOSINUSITIS PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	Parainfluenza virus types 1, 2, 3, 4	MRSA <sup>1</sup>
Human coronavirus (4 types)	Respiratory Syncytial Virus	<i>Staphylococcus aureus</i>
Human metapneumovirus	Rhinovirus	<i>Streptococcus pneumoniae</i>
Influenza A - Human influenza	<i>Haemophilus influenzae</i>	<i>Streptococcus pyogenes</i> (Group A)
Influenza A - H1N1-09	<i>Haemophilus influenzae</i> (Type B)	
Influenza B	<i>Moraxella catarrhalis</i>	

### Collection Procedures:

Nasopharyngeal Aspirate/Wash...	20
Nasopharyngeal Swab .....	20

## SEXUALLY TRANSMITTED DISEASE PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Atopobium vaginae</i>	<i>Mycoplasma genitalium</i>	<i>Trichomonas vaginalis</i>
<i>Chlamydia trachomatis</i>	<i>Mycoplasma hominis</i>	<i>Ureaplasma urealyticum</i>
<i>Gardnerella vaginalis</i>	<i>Neisseria gonorrhoeae</i>	

### Collection Procedures:

Endocervical Swab .....	23
Vaginal Swab .....	24
ThinPrep® Pap Solution .....	21
Male Urethral Swab .....	24
Urine Specimen for STD Testing...	23

**DISCLAIMER:** The Diatherix Laboratories Sexually Transmitted Disease Panels are not recommended for evaluation of suspected sexual abuse or for other medico-legal indications.

**NOTE:** When collecting a urethral swab or a urine specimen from a male or female patient, the patient should not have urinated for at least an hour before the specimen is collected. The first morning urine specimen is preferred due to the large amount of cells usually present.

ThinPrep® pap solution is stable for 30 days.

Because certain organisms are intracellular, there must be enough human cells present to detect the organism. Diatherix tests the specimen for human DNA to ensure that an adequate number of cells are present for a valid result.

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

# DIATHERIX TEST PANELS

## STAPHYLOCOCCUS DIFFERENTIATION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

MRSA<sup>1</sup>

*Staphylococcus aureus*

PVL<sup>2</sup> gene

MRCoNS<sup>3</sup>

Coagulase-Negative *Staphylococci*

*Staphylococcus epidermidis*

### Antibiotic Resistance:

Aminoglycosides

Cephalosporin

Erythromycin/Clindamycin

Methicillin

Tetracycline

### Collection Procedures:

General Swab (wound, etc<sup>4</sup>) .....19

Nasal Swab.....20

Synovial Fluid .....21

Clean Catch Urine Specimen .....22

## UPPER RESPIRATORY INFECTION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21

Enterovirus group

Human coronavirus (4 types)

Human metapneumovirus

Influenza A - Human influenza

Influenza A - H1N1-09

Influenza B

Parainfluenza virus types 1, 2, 3, 4

Rhinovirus

*Haemophilus influenzae*

*Haemophilus influenzae* (Type B)

*Moraxella catarrhalis*

*Streptococcus pneumoniae*

*Streptococcus pyogenes* (Group A)

### Collection Procedures:

Nasopharyngeal Aspirate/Wash...20

Nasopharyngeal Swab .....20

Throat Swab .....19

Bronchial Aspirate.....21

Sputum Specimen Swab .....21

<sup>1</sup> Methicillin-resistant *Staphylococcus aureus*

<sup>2</sup> Pantone-Valentine leukocidin

<sup>3</sup> Methicillin-resistant Coagulase-Negative *Staphylococci*

<sup>4</sup> Axillary and perineal areas are also useful in detecting MRSA colonization

# DIATHERIX TEST PANELS

## URINARY TRACT INFECTION PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

<i>Enterobacter cloacae</i>	<i>Klebsiella pneumoniae</i>
<i>Enterococcus faecalis</i>	<i>Proteus mirabilis</i>
<i>Escherichia coli</i>	<i>Pseudomonas aeruginosa</i>

### Collection Procedure:

Clean Catch Urine Specimen . . . . .22

**NOTE:** When collecting a urine specimen from a male or female patient, the patient should not have urinated for at least an hour before the specimen is collected.

## VIRAL RESPIRATORY PANEL

This panel utilizes TEM-PCR to detect molecular targets that identify:

Adenovirus types 3, 4, 7, 21	Human metapneumovirus	Parainfluenza virus types 1, 2, 3, 4
Enterovirus group	Influenza A - Human influenza	Respiratory Syncytial Virus
Human bocavirus	Influenza A - H1N1-09	Rhinovirus
Human coronavirus (4 types)	Influenza B	

### Collection Procedures:

Nasopharyngeal Aspirate/Wash . . .	20
Nasopharyngeal Swab . . . . .	20
Throat Swab . . . . .	19
Bronchial Aspirate . . . . .	21
Sputum Specimen Swab . . . . .	21

# SPECIMEN COLLECTION PROCEDURES

## GENERAL SWAB

---

### Wound/Abscess

*Syringe aspiration of purulent material from a loculated, palpable lesion is preferred.*

1. The surface of the wound/abscess should be carefully cleansed and debrided using sterile gauze and saline before attempting to aspirate the specimen.
2. Aspirate the specimen and place 0.5 to 1.0 mL of the aspirate directly into an ESwab™ (white top) transfer tube and screw the top on tightly.

### Open, Draining Wounds, and Decubitus Ulcers

1. Use the ESwab™ Collection Kit (white top tube).
2. Cleanse and debride the wound with sterile gauze and saline.
3. Exudate and brushings of the wound base (including advancing margins) should be collected using the swab from an ESwab™ collection kit.
4. Without contaminating the swab, place the swab into the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

### Throat, Ear, Eye, and Dermal (other than Wound, Ulcer, and Abscess)

1. Use the ESwab™ Collection Kit (white top tube).
2. Open the ESwab™ Collection Kit and remove the swab and transfer tube, being careful to prevent contamination.
3. Rub the swab on the area to be tested. Any infectious site can be swabbed with the ESwab™ for the appropriate panel.
4. Without contaminating the swab, place the swab into the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

For general video instructions on using the ESwab™ Collection Kit click the [Copan ESwab™ Training Video](http://www.diatherix.com/videos.html) link at <http://www.diatherix.com/videos.html>



# SPECIMEN COLLECTION PROCEDURES

## NASOPHARYNGEAL (NP)

---

### NP Aspirate/Wash Collection

*The diagnosis of otitis media, sinusitis, and infections of the upper respiratory tract in general is best achieved using a properly collected NP wash/aspirate.*

1. Place the aspirate directly into an ESwab™ transport tube
2. Screw the top tightly on the transport tube.

### NP Swab Collection

1. Use the ESwab™ Collection Kit (white top tube) along with a nasopharyngeal flocked swab (packaged separately).
2. Open the nasopharyngeal swab. Ask the patient to attempt to cough twice, if possible. Then insert the nasopharyngeal swab through one nostril straight back along the floor of the nasal passage until reaching the posterior wall of the pharynx. Rotate the swab for 5 to 10 seconds, leave it in place for a few seconds, and then slowly withdraw.
3. Open the ESwab™ kit and remove the transport tube only. Without contaminating the swab, place the NP swab into the white top transport tube all the way to the bottom and rotate the swab 5 times in the solution. Remove and discard the swab.
4. Screw the top tightly on the transport tube.

For a video demonstrating the NP Swab procedure click the Nasopharyngeal Swab Collection Video link at <http://www.diatherix.com/videos.html>

## NASAL SWAB

---

1. Use the ESwab™ Collection Kit (white top tube).
2. If the patient has nasal discharge, ask the patient to attempt to clear the discharge by blowing his/her nose into non-scented tissue paper.
  - *Do not clear the discharge with swabs, as this might be excessively traumatic. Assist children whenever necessary.*
3. Remove the swab and transfer tube from the collection kit. Do not contaminate.
4. Carefully insert the swab into the patient's nostril up to 1 inch from the edge of the nare.
5. Rub the swab 5 times against the surface of the nare. Insert the same swab into the second nostril and roll the swab 5 times against the surface of the nare.
  - *Sampling the inside portion of the alar rima is also useful in determining nasal carriage of *S. aureus*.*
6. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom of the tube. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
7. Screw the top tightly on the transport tube.

# SPECIMEN COLLECTION PROCEDURES

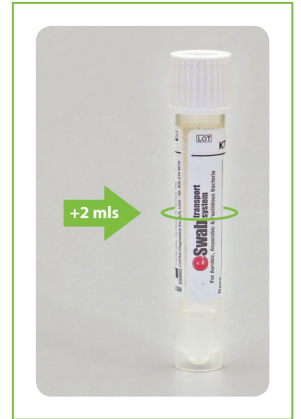
## FLUID SPECIMEN

### Urine (not STD), Synovial Fluid, Bronchial Aspirate, or ThinPrep® Pap Solution\*

1. Use the ESwab™ Collection Kit (white top tube).
2. Open the collection kit and discard the swab.
  - Add approximately 2 ml of the specimen fluid to the 1 ml of fluid already in the tube. Do not fill the tube to the top.
3. Screw the top tightly on the transport tube.

#### \*ThinPrep® Pap Solution ONLY

Pour out all of the media solution in the ESwab™ tube. Then add approximately 2 to 3 ml of the ThinPrep® pap solution to the empty tube. Do not fill the tube to the top.



## SPUTUM OR STOOL

1. Use the ESwab™ Collection Kit (white top tube).
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Both sputum and stool samples should be carefully examined to identify portions of the specimen; e.g. blood and mucous flecks, that often contain infectious pathogens. These areas of the specimen should be carefully collected by placing the ESwab™ tip directly into the representative area identified.
4. Without contaminating the swab, place the swab in the ESwab™ transport tube all the way to the bottom of the tube. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

## RECTAL SWAB (GASTROINTESTINAL ILLNESS)

1. Use the ESwab™ Collection Kit (white top tube).
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Insert the tip of the sterile flocked swab approximately 1 inch beyond the anal sphincter.
4. Carefully rotate the swab to sample the anal crypts then withdraw the swab.
5. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
6. Screw the top tightly on the transport tube.

# SPECIMEN COLLECTION PROCEDURES

## CLEAN CATCH URINE SPECIMEN (NOT FOR STD TESTING)

---

1. Instruct the patient with the instructions provided below.
2. Follow the Fluid Specimen Collection Procedure (page 21) after obtaining the specimen.

### Patient Instructions:

1. Wash hands with soap and warm water.
2. Follow gender specific instructions:
  - **Females:** Spread the labia (folds of skin) apart with one hand and wipe with a towelette. Wipe from front to back. Repeat this process the second time with a fresh towelette.
  - **Males:** If uncircumcised, retract the foreskin.
3. Follow gender specific instructions:
  - **Females:** Continue holding the labia apart. As you start to urinate, allow a small amount of urine to fall into the toilet bowl. (This clears the urethra of contaminants). Do not touch the inside of the collection cup.
  - **Males:** Wipe the end of the penis with a towelette. As you start to urinate, allow a small amount of urine to fall into the toilet bowl. (This clears the urethra of contaminants). Do not touch the inside of the collection cup.
4. After the urine stream is well established, pass the collection cup into the urine stream and, after the cup is ½ full, remove the cup from the urine stream and finish urinating into the toilet bowl.
5. Screw the lid on the cup tightly (do not touch inside of cup or lid). Give the sealed cup to the nurse or attendant.

For a video demonstrating the clean catch urine procedure click the Clean Catch Urine Collection Video link at <http://www.diatherix.com/videos.html>

## VAGINAL/RECTAL SWAB (PREGNANCY RELATED GBS COLONIZATION)

---

*Vaginal/Rectal swab is the specimen of choice for pregnancy related GBS colonization.*

1. Use the ESwab™ Collection Kit (white top tube). **Do not use the orange top Genital Health tube.**
2. Remove the swab and transfer tube from the collection kit. Do not contaminate.
3. Swab the lower vagina (vaginal introitus), followed by the rectum (insert the swab through the anal sphincter) using the same swab. Move the swab from side to side, or rotate the swab at the collection site; allowing a few seconds for the organisms to be absorbed by the swab.
  - *Cervical specimens and speculum assisted collections are not recommended.*
4. Without contaminating the swab, place the swab in the white top transport tube all the way to the bottom. You may either break the swab at the scored breakpoint indication line or rotate the swab 5 times in the solution and discard the swab.
5. Screw the top tightly on the transport tube.

# SPECIMEN COLLECTION PROCEDURES

## URINE SPECIMEN FOR STD TESTING (MALE OR FEMALE)

---

1. Use the Genital Health Collection Kit (orange top tube).
2. Patient should not have urinated for at least one hour prior to sample collection. *First morning specimen is preferred.*
3. Specimens collected on female patients should be obtained **without** cleansing the external genitalia.
4. Collect approximately 5-10 mL of the first-catch urine into a preservative free specimen collection cup. **Please note that larger volumes will dilute the specimen and yield false negative results.** After collecting the desired amount of urine, the specimen container can be removed from the stream so that the void can be completed.
5. Open the Genital Health Collection Kit and discard the collection swabs.
6. Transfer the urine (2-3 mL) into an orange top transport tube using the plastic transfer pipette.
7. Recap the transport tube carefully, ensuring that the cap seals tightly.
8. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

## ENDOCERVICAL SWAB

---

1. Use the Genital Health Collection Kit (orange top tube).
2. Open the collection kit and discard the plastic disposable pipette. Remove the sterile endocervical swab from the wrapper being careful not to contaminate the swab.
3. Insert the white tip of the specimen swab into the endocervix canal with minimal contact with the vaginal wall.
4. Gently rotate the swab for 15 seconds to ensure adequate sampling.
5. Withdraw the swab carefully avoiding unnecessary contact with the vaginal wall.
6. Place the swab into the orange top transport tube, rotate the swab 5 times in the solution, and discard the swab.
7. Recap the transport tube carefully, ensuring that the cap seals tightly.
8. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

# SPECIMEN COLLECTION PROCEDURES

## VAGINAL SWAB

---

1. Use the Genital Health Collection Kit (orange top tube).
2. Open the Genital Health Collection Kit and discard the plastic disposable pipette. Remove the sterile vaginal swab from the wrapper being careful not to contaminate the swab by touching it to any surface.
3. Insert the white tip of the specimen swab about two inches (5 cm) into the opening of the vagina<sup>1</sup>.
4. Gently rotate the swab for 15 to 30 seconds against the sides of the vagina to ensure adequate sampling.
5. Withdraw the swab carefully.
6. Handle the cap and tube carefully to avoid contamination.
7. Without contaminating the swab, place the swab into the orange top transport tube all the way to the bottom. Carefully break the swab at the line on the shaft; use care to avoid splashing of contents.
8. Recap the transport tube carefully. Ensure the cap seals tightly.
9. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

## MALE URETHRAL SWAB

---

1. The patient should not have urinated for at least one hour prior to sample collection.
2. Open the Genital Health Collection Kit and discard the plastic disposable pipette. Remove the sterile urethral swab from the wrapper being careful not to contaminate the swab by touching it to any surface.
3. Insert the white tip of the specimen swab  $\frac{3}{4}$  to  $1\frac{1}{2}$  inches (2 to 4 cm) into the urethra.
4. Gently rotate the swab for 2 to 3 seconds to ensure adequate sampling.
5. Withdraw the swab carefully.
6. Handle the cap and tube carefully to avoid contamination.
7. Without contaminating the swab, place the swab in the orange top transport tube all the way to the bottom. Rotate the swab 5 times in the solution and discard the swab.
8. Recap the transport tube carefully. Ensure the cap seals tightly.
9. Label the transport tube with the patient name and date collected using the adhesive label provided or place the barcode label from the requisition on the transport tube.

<sup>1</sup> A sampling of vaginal vault fluid may improve the detection of bacterial vaginosis pathogens.

## RESPIRATORY SPECIMEN COLLECTIONS

---

### Upper Respiratory Tract (Otitis Media, Rhinitis, and Acute Sinusitis)

To avoid invasive techniques such as tympanocentesis and imaging guided percutaneous aspiration of sinus cavities, properly collected nasopharyngeal swabs or aspirates are useful methods of collecting upper respiratory tract infections. Proper positioning of the patient (prone with head tilted to the posterior) will allow the insertion of the collection device (catheter for collection of NP washes or a flocked swab) into the nasopharyngeal pool that accumulates the drainage of the eustation tube, the sinus cavities, and, to a lesser extent, the posterior pharynx. Swabs should be left in contact with the NP pooled secretions to absorb as much diagnostic material as possible.

### Lower Respiratory Tract (Bronchitis and Pneumonitis)

The accurate diagnosis of lower respiratory tract infection is totally dependent upon the quality of the specimen collected. Several methods have been employed to screen sputum specimens and to improve the reliability of lower airway collections using bronchial washing or specimens obtained via bronchoscopy. It suffices to say that lower respiratory secretions obtained via sputum collection, bronchial alveolar lavage, bronchoscopy, or transtracheal aspiration that are optimized to reduce the likelihood of oropharyngeal contamination are preferred.

The diagnostic yield of sputum specimen collections can be improved by thoroughly rinsing the oropharyngeal cavity with water before instructing the patient to produce a “deep cough” specimen. Many patients are unable to provide a proper sputum specimen and induction techniques with the assistance of respiratory therapists may be required. Suctioning of lower airway secretions can also be considered.

### Pharyngitis

The sensitivity of any test used to rule out the presence of Group A Streptococcal Pharyngitis is dependent upon a properly collected swab obtained from the posterior pharynx and tonsils. Although the majority of pharyngitis cases are viral in origin, ruling out the presence of Group A Strep is essential. Proper visualization of the posterior oropharynx is required to identify areas of inflammation and exudate that may be present. Depression of the tongue and careful introduction of the swab to the site of inflammation is an important part of the collection technique that avoids contamination of the specimen with oral secretions.



## TUBE SELECTION REFERENCE

Panel	Specimen Containers	
	Copan ESwab™ ①	Genital Health ②
Atypical Pneumonia	●	
Bacterial Pneumonia	●	
Bacterial Vaginosis	●	●
Bronchitis	●	
<i>C. difficile</i> Toxin B gene	●	
Candidiasis	●	●
CT + NG + <i>T. vaginalis</i> *		●
Ear Nose & Throat	●	
Gastrointestinal	●	
Group B <i>Streptococcus</i>	●	
Herpes Simplex Virus	●	●
HPV High Risk Typing	●	●
Infectious Disease	●	
Influenza	●	
Pediatric Respiratory	●	
Pharyngitis	●	
Respiratory Infection	●	
Rhinosinusitis	●	
STD 5 *		●
Sexually Transmitted Disease *		●
<i>Staphylococcus</i> Differentiation	●	
Upper Respiratory Infection	●	
Urinary Tract Infection	●	
Viral Respiratory	●	



\* Must be submitted in the Genital Health tube (orange top), even when ordered in combination with another panel.

# CLIENT SUPPLIES

## 1 ESwab™ Collection Kit Supplies

- a ESwab™ White Top Tube with Standard Flocked Swab
- b Biohazard Bag

*Nasopharyngeal Flocked swab is available by request.*



## 2 Genital Health Collection Kit Supplies

- a Diatherix Orange Top Tube
  - Standard Nylon Flocked Swab
  - Male Urethral or Endocervical Nylon Flocked Swab
  - Urine Pipette
- b Biohazard Bag



## 3 Patient Take Home Stool Collection Kit

- English/Spanish Patient Instructions
- Latex Free Glove
- Biohazard Bag
- Absorbent Pad
- ESwab™ White Top Tube With Standard Flocked Swab



## 4 Stool Collection Device

## 5 FedEx® UN3373 Clinical Pak



## 6 Prepaid FedEx® Label

## 7 Laboratory Request Form



## 8 Specimen Shipping Box



# SAMPLE SUPPLY ORDER FORM

## NOTES

Supplies can be ordered via phone, fax or email.

The order form can be filled out electronically using Adobe Reader, it can then be saved, printed, faxed or emailed by clicking the submit button at the bottom.

A current PDF of this form can always be found at [diatherix.com](http://diatherix.com).

**CLIENT SUPPLY ORDER FORM**

Phone: 877.820.8047 / Fax: 256.327.9858  
Email: [supplies@diatherix.com](mailto:supplies@diatherix.com)

– All supply orders are shipped via FedEx® Ground.

– Orders received after 3:00 PM CST may be shipped the following business day.

Client Number: \_\_\_\_\_ Client Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Phone: \_\_\_\_\_ Email: \_\_\_\_\_

Comments:

**Specimen Collection Supplies**

QTY	KIT
<input type="checkbox"/>	ESwab™ Collection Tube (White Top Tube)
<input type="checkbox"/>	ESwab™ Collection Bag
<input type="checkbox"/>	Genital Health Collection Tube (Orange Top Tube)
<input type="checkbox"/>	Genital Health Collection Bag
<input type="checkbox"/>	Patient Stool Collection Kit
<input type="checkbox"/>	Patient Stool Collection Device

See Client Service Manual for list of items in each kit at [www.diatherix.com/Client-Service-Manual.html](http://www.diatherix.com/Client-Service-Manual.html)


**Shipping Supplies**

QTY	ITEM
<input type="checkbox"/>	1 Specimen Shipping Boxes
<input type="checkbox"/>	2 FedEx® Clinical Pak
<input type="checkbox"/>	3 FedEx® Shipping Label


**Other Supplies**

QTY	ITEM
<input type="checkbox"/>	4 Preprinted Requisition Form
<input type="checkbox"/>	5 Nasopharyngeal Swab


1




2




3




4




5





Click to email this order to [supplies@diatherix.com](mailto:supplies@diatherix.com): 

SUBMIT

 **DIATHERIX®**

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# SAMPLE TEST REQUISITION

## DIRECTIONS

Complete each section following any instructions given to the right of the section header.

**Note:** At least one checkbox must be selected in the Test/Panel Selection section. *Certain panels may be combined on the same specimen provided the specimen is acceptable for each panel requested.*

In the Billing Information section, either attach a face sheet or complete the form with the applicable information.

 <b>DIATHERIX</b>		<b>LABORATORY REQUEST</b>		<small>Diatherix Laboratories, Inc. 601 Genome Way / Suite 2100 / Huntsville, AL 35806 Phone: 866.979.4242 / Fax: 256.327.0984 / CLIA ID: 01D1085737</small>	
<b>SPECIMEN INFORMATION:</b> Print patient's name on the label and apply along the length of specimen tube. Print legibly to complete the fields below including ICD-9 / chief complaint(s).					
Peel label:					
Patient:		First Name _____ MI _____ Last Name _____		Gender: <input type="checkbox"/> M <input type="checkbox"/> F DOB: ____ - ____ - ____ mm dd yyyy	
Specimen:		Source: _____ Type: _____		Collected: ____ - ____ - ____ mm dd yyyy Time: <input type="checkbox"/> am <input type="checkbox"/> pm	
ICD-9 Code(s) or Chief Complaint: _____					
Optional: Patient ID: _____ Client specimen ID #: _____ Ethnic origin: _____					
<b>PROVIDER INFORMATION:</b> Print the ordering provider's name, and if applicable, the supervising physician.					
Ordering Provider:		First Name _____ Last Name _____		NPI Number _____	
Supervising Physician:		First Name _____ Last Name _____		NPI Number _____	
<b>TEST/PANEL SELECTION:</b> Multiple panels may be selected for a specimen provided there is sufficient quantity and the specimen is appropriate for each panel.					
<input type="checkbox"/> Respiratory Infection Panel		<input type="checkbox"/> Atypical Pneumonia Panel		<input type="checkbox"/> Sexually Transmitted Disease Panel	
<input type="checkbox"/> Upper Respiratory Infection Panel		<input type="checkbox"/> Bronchitis Panel		<input type="checkbox"/> CT+NG+T.vaginalis Panel	
<input type="checkbox"/> Pediatric Respiratory Panel		<input type="checkbox"/> Rhinosinusitis Panel		<input type="checkbox"/> Herpes Simplex Virus Panel	
<input type="checkbox"/> Pharyngitis Panel		<input type="checkbox"/> Infectious Disease Panel		<input type="checkbox"/> HPV High Risk Typing Panel	
<input type="checkbox"/> Viral Respiratory Panel		<input type="checkbox"/> Staphylococcus Differentiation Panel		<input type="checkbox"/> STD 5 Panel	
<input type="checkbox"/> Bacterial Pneumonia Panel		<input type="checkbox"/> Clostridium difficile Toxin B Gene		<input type="checkbox"/> STD + HSV Panel	
<input type="checkbox"/> Ear Nose & Throat Panel		<input type="checkbox"/> Gastrointestinal Panel		<input type="checkbox"/> STD + Candidiasis Panel	
<input type="checkbox"/> Influenza Panel				<input type="checkbox"/> Bacterial Vaginosis Panel	
				<input type="checkbox"/> Candidiasis Panel	
				<input type="checkbox"/> Group B Streptococcus	
				<input type="checkbox"/> Urinary Tract Infection Panel	
Comment: _____					
<b>BILLING INFORMATION:</b> After selecting bill class, you may attach a face sheet and insurance card copy containing the patient and insurance information requested below.					
Bill Class: <input type="checkbox"/> Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient Self Pay <input type="checkbox"/> Client Bill Other _____					
<b>Patient Information:</b> Social Security Number _____ Phone Number _____					
Address _____ Street _____ City _____ State _____ Zip _____					
<b>Primary Insurance:</b> Policy/ID# _____ Group #: _____					
Subscriber: Name (if other than patient): _____ Relationship to patient: _____					
Insurance company: Name: _____ Phone: _____					
Address (where claims are submitted): _____ Street _____ City _____ State _____ Zip _____					
Is this a Worker's Comp claim? <input type="checkbox"/> Yes <input type="checkbox"/> No Date of Injury: ____ - ____ - ____ Adjuster's name/phone: _____					
<b>Secondary Insurance:</b> Policy/ID# _____ Group #: _____					
Subscriber: Name (if other than patient): _____					
Insurance company: Name: _____ Phone: _____					
Address (where claims are submitted): _____ Street _____ City _____ State _____ Zip _____					
<small>Physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient.</small>					
Document: FO-110601 Rev. 3-100314					


# SAMPLE LABORATORY REPORT

## NOTES

A Laboratory Report is generated for each individual panel ordered.

Reports can be received via fax, email, Web Client online portal, and direct computer interface.

To review examples of other panel specific reports, visit [www.diatherix.com/test-catalog.html](http://www.diatherix.com/test-catalog.html) and select the desired panel.

 <b>DIATHERIX<sup>®</sup></b>		<b>LABORATORY REPORT</b>		<small>Diatherix Laboratories, Inc. 601 Genome Way / Suite 2100 / Huntsville, AL 35806 Phone: 866.979.4242 / Fax: 256.327.0984 / CLIA ID: 01D1085737</small>	
<b>PATIENT:</b>			<b>ORDERING PHYSICIAN:</b>		
Gender:	Age:	DOB:	ID:	Name:	
			Ethnicity:	Phone:	
<b>SPECIMEN:</b>			<b>CLIENT:</b>		
Source:		Collected:		Name:	
Type:		Received:		Code:	
Specimen ID:		Reported:		Address:	
Accession ID:					
<b>Respiratory Infection Panel:</b>		<b>DETECTED</b>	<b>NOT DETECTED</b>	<b>COMMENTS:</b>	
Viral Infections Adenovirus Enterovirus group Human Bocavirus Human Coronavirus Human Metapneumovirus Influenza A - Human Influenza Influenza A - H1N1-09 Influenza B Parainfluenza Respiratory Syncytial Virus Rhinovirus  Bacterial Infections Acinetobacter baumannii Bordetella pertussis Chlamydomphila pneumoniae Haemophilus influenzae Haemophilus influenzae Type B Klebsiella pneumoniae Legionella pneumophila Moraxella catarrhalis MRSA Mycoplasma pneumoniae Neisseria meningitidis Pantom-Valentine leukocidin (PVL) gene Pseudomonas aeruginosa Staphylococcus aureus Streptococcus pneumoniae Streptococcus pyogenes (Group A Strep)  Antibiotic Resistance Aminoglycosides resistance Cephalosporin resistance (Staphylococcal) Erythromycin/Clindamycin resistance Methicillin resistance (Staphylococcal) Tetracycline resistance					
<small>Testing performed by TEM-PCR<sup>™</sup> (Target Enriched Multiplex Polymerase Chain Reaction)      Patent US 7,851,148 B2      <b>Linking Diagnostics to Therapeutics<sup>™</sup></b>  <small>Document: FO-080407 Rev 4-122214</small> </small>					

## ORDER CODES FOR PANELS

Order Code	Diatherix Test Panel
<b>APP</b>	Atypical Pneumonia Panel
<b>BPP</b>	Bacterial Pneumonia Panel
<b>BVP</b>	Bacterial Vaginosis Panel
<b>BRN</b>	Bronchitis Panel
<b>CAND</b>	Candidiasis Panel
<b>GNT</b>	<i>Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis</i>
<b>CDIF</b>	<i>Clostridium difficile</i> Toxin B Gene
<b>ENT</b>	Ear Nose & Throat Panel
<b>GP</b>	Gastrointestinal Panel
<b>GBS</b>	Group B <i>Streptococcus</i>
<b>HSV</b>	Herpes Simplex Virus Panel
<b>HPV</b>	HPV (Human Papillomavirus) High Risk Typing Panel
<b>IDP</b>	Infectious Disease Panel
<b>FLU</b>	Influenza Panel
<b>PRP</b>	Pediatric Respiratory Panel
<b>PHP</b>	Pharyngitis Panel
<b>RES</b>	Respiratory Infection Panel
<b>RHP</b>	Rhinosinusitis Panel
<b>STD</b>	Sexually Transmitted Disease Panel
<b>GNTH</b>	STD 5
<b>SDP</b>	<i>Staphylococcus</i> Differentiation Panel
<b>URI</b>	Upper Respiratory Infection
<b>UTI</b>	Urinary Tract Infection Panel
<b>VRP</b>	Viral Respiratory Panel
<b>BVPCAND</b>	Bacterial Vaginosis + Candidiasis Panel
<b>STDCAND</b>	Sexually Transmitted Disease + Candidiasis Panel
<b>STDH</b>	Sexually Transmitted Disease + Herpes Simplex Virus Panel
<b>STDHCAND</b>	Sexually Transmitted Disease + Herpes Simplex Virus + Candidiasis
<b>STDMGN</b>	CT + NG + <i>T. vaginalis</i> + <i>M. genitalium</i>



## CLIENT NOTES

### WEBCLIENT ACCESS INFORMATION:

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Username: \_\_\_\_\_

Click **Client Log-In** to enter WebClient from any page on [diatherix.com](http://diatherix.com)

Password: \_\_\_\_\_

During the first login, please change the password to ensure privacy.

### ADDITIONAL NOTES:

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